APPLICATION FOR PATENT

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TITLE:

FOOD BAR FOR TREATING MUSCULOSKELETAL DISORDERS

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Christian Heausler

SPECIFICATION

FIELD

[0001] Embodiments relate to a food bar used to treat an inflammatory tissue or musculoskeletal disorders in mammals that involves tissue that is underperfused and inflamed such as muscles and joints, tendons and ligaments.

BACKGROUND

[0002] The present application claims priority to co-pending U.S. Patent Application Serial No 10/241,542 filed on September 11, 2002.

[0003] A need has existed for a large convenient dosage of glucosamine to be taken in one daily dose that can be quickly absorbed into the bloodstream. The large convenient dosage of glucosamine would thereby bypass the gut and eliminate the adverse reactions of the supplement's elemental ingredients as well as protect and buffer the lining of the stomach from the high dosages of the supplement's elemental ingredients. The large convenient dosage of glucosamine would also buffer the glucose levels in the blood and significantly reduce or eliminate the possible adverse effects of the supplement's essential ingredients.

[0004] The large convenient dosage of glucosamine would also make it possible to administer a one time daily large dose of the supplement that is fast absorbing, uses a powerful vasodilatation system, is tasteless in most liquids, odorless, non- steroidal, has no adverse symptoms of nausea, heartburn, diarrhea, constipation or headache as well as perfusing underperfused tissue by saturating the tissue, increases mobility of a mammal in all directions, decreasing inflammation, maintaining cartilage viability, increasing strength, muscle flexibility and health of tendons and ligaments, as well as increasing endurance and performance, and is also cost effective and capable of mass production.

[0005] Petrus US Patent No 6,399,093 discloses a method and composition for the treatment of musculoskeletal disorders in mammals by the application of a topical composition comprising a permeation enhancing amount of one or more penetration enhancers, and one or more bio-affecting agents to provide anti-inflammatory relief and analgesia to the applied body part.

[0006] The present supplement is beneficial because it fast absorbing, non-steroidal, and a vasodilator. The additive also is a one-time daily large dose. No symptoms of nausea, heartburn, constipation, diarrhea, and headaches are associated with the present supplement. In addition, the present supplement contains a high quantity of glucosamine.

[0007] The compoistion of the present supplement is also cost effective since it is capable of being mass-produced in individual food bars.

[0008] The present supplement is also beneficial because it perfuses underperfused tissues by saturating the tissue, increasing mobility in all directions, decreasing inflammation, maintaining cartilage viability, increasing strength, increasing muscle flexibility, and increasing endurance.

SUMMARY

[0009] The food bar usable for treating arthritic conditions is made of from about 250 mg to about 2500 mg 2-amino-2-deoxyglucose sulfate; 2-amino-2-deoxyglucose sulfate hydrochloride; n-acetyl 2-amino-2-deoxyglucose sulfate; and combinations thereof; from about 200 mg to about 2000 mg of a protein; from about 10 mg to about 8000 mg of a flavoring; from about 100 mg to about 2500 mg of Vitamin B, Vitamin C, Vitamin E or complexes thereof; and from about 1000 mg to about 9000 mg of a fiber.

[00010] A method for improving joint mobility in a subject comprising administering to the subject an amount of the food bar involves administering to a subject an amount of the supplement on a regular basis.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00011] Before explaining the present composition in detail, it is to be understood that the composition is not limited to the particular embodiments and that it can be practiced or carried out in various ways.

[00012] The food bar is an ingestible meal bar is usable for treating an inflammatory tissue or musculoskeletal disorders in a mammal involving tissue that is underperfused tissue, inflamed joints, or inflamed muscles, tendons and ligaments. The dosage amount is made from a glucosamine sulfate, a glucosamine hydrochloride, and an n-acetyl glucosamine and combinations thereof. Once daily dosages of the food bar are administered for about 10 to about 36 consecutive days, the user shows positive results regarding the treatment of musculoskeletal disorders.

[00013] The ingestible supplement is beneficial because the supplement perfuses underperufsed tissues. The supplement saturates the tissue, increases mobility in all directions, decreases inflammation, maintains cartilage viability, increases strength, increases muscle flexibility, and increases endurance.

[00014] Musculoskeletal disorders cover arthritis conditions of all types, bone injuries and disorders, muscle injuries and disorders, joint and ligament injuries and disorders, tendon injuries and disorders and the like.

[00015] The food bar uses an ingestible amount of glucosamine for treating an inflammatory tissue or musculoskeletal disorders in a mammal involving tissue that is underperfused tissue, inflamed joints or inflamed muscles and tendons. The dosage is a glucosamine sulfate, glucosamine hydrochloride, and an n-acetyl glucosamine and combinations thereof.

[00016] Glucosamine, whose scientific name is 2-amino-2-deoxyglucose sulfate, occurs naturally in the human body. Glucosamine provides strength, flexibility, and elasticity to cartilage and connective tissue by stimulating the production of glycosaminoglycans. Glucosamine also decreases inflammation that can lead to joint destruction. Glucosamine is involved in the formation of nails, tendons, skin, eyes, bones, ligaments, and heart valves. More importantly, glucosamine contributes to the strength and integrity of joint structures. Connective tissue and cartilage naturally contain high concentrations of glucosamine. When sufficient levels of glucosamine are present, cartilage retains its ability to hold water and act as a shock absorber. Glucosamine sulfate is a simple molecule composed of glucose, an amine, and sulfur. The joints are naturally rich in sulfur molecules, which form important cross-linkages with other molecules. These cross-linkages provide cartilage with its strength, structure, and shock-absorbing qualities. The strength, structure, and shock-absorbing qualities along with glucosamine's absorbability quality makes glucosamine sulfate the preferred form of supplemental glucosamine.

[00017] Each person produces a certain amount of glucosamine. As people age, the body no longer produces enough glucosamine causing musculoskeletal disorders such as arthritic conditions, deformed joints and limited joint and tendon movement. Numerous double-blind, placebo controlled glucosamine studies have been published, all reporting that glucosamine was indeed very effective in treating osteoarthritis and reducing inflammation and that its use is long-term safe. The studies have also shown that glucosamine provided in liquid form is absorbed more quickly, much more fully, and provides greater and longer lasting relief.

[00018] Methylsulfonylmethane (MSM) is a natural form of organic sulfur found in all living organisms. MSM is prevalent throughout the human body. MSM is an important food that plays many roles in the body, including the stimulation of the growth of healthy skin, hair and nails. MSM is needed by the body for healthy, connective tissues and joint function, proper enzyme activity and hormone balance, along with the proper function of the immune system. MSM is highly soluble in both oil and water.

[00019] As oxygen is transported from the lungs to the mitochondria, oxygen goes through a number of stages with continually decreasing oxidation potential or effective oxygen concentration. MSM easily and rapidly diffuses through the hydrophilic cell cytoplasm as well as the hydrophobic cell membranes. MSM has no barriers. The human body has no other molecules naturally occurring in our bodies similar to MSM. Oxygen transport is handled by passing it between different molecules that are hydrophilic in the cytoplasm and hydrophobic in the cell membranes

[00020] The food bar contemplates variations in the dosage amounts.

[00021] The food bar for arthritis preferably uses from about 250 mg to about 2500 mg of 2-amino-2-deoxyglucose sulfate; 2-amino-2-deoxyglucose sulfate hydrochloride; n-acetyl 2-amino-2-deoxyglucose sulfate, and combinations thereof.

[00022] The food bar also includes from about 200 mg to about 2000 mg of protein. Examples of proteins contemplated are whey proteins, soy or vegetable protein, urea, caseins and calcium caseinate, legume proteins, blue green micro algae proteins, nut and seed proteins and fish and animal proteins derived from eggs, meat or milk and combinations thereof. Blue-green micro-algae form spiral filaments or chains that as a dietary supplement that contain 65% protein in the dried state.

[00023] Additionally, the food bar can have from about 10 mg to about 8000 mg of a flavoring extract, such as syrup or sugar. The flavorings can be natural or artificial or alone or in combinations.

[00024] Various vitamins can be used. The food bar can include from about 100 mg to about 2500 mg of Vitamin B, Vitamin C, Vitamin E, zinc oxide, copper gluconate and potassium, or complexes of these vitamins.

[00025] If Vitamin B is used, the preferred dosage is from about 10 mg to about 500 mg Vitamin B. The preferred Vitamin B is a Vitamin B complex, The Vitamin B complex includes thiamine (Vitamin B1), riboflavin (Vitamin B2), niacin (Vitamin B3), pyridoxine (Vitamin B6), folic acid (Vitamin B9), cyanocobalamin (Vitamin B12), pantothenic acid, and biotin. The Vitamin B family aid metabolic activity and

also produces energy. The Vitamin B family is also involved in making red blood cells that carry oxygen throughout the body and is necessary for every part of the body to work properly.

[00026] If Vitamin C is used, the preferred dosage is from about 250 mg to about 2,500 mg. Vitamin C comes in two basic forms: ascorbic acid and calcium ascorbates. Vitamin C is naturally found in citrus fruits, such as oranges, grapefruit, lemons, mangos, and the like, and in many green vegetables, such as asparagus, broccoli, spinach, green peppers, and peas, tomatoes, potatoes and cabbage. Ascorbic acid is the standard form of vitamin C. Examples of Vitamin C usable in the invention are ascorbic acid, mineral ascorbates, calcium ascorbates, a potassium ascorbate with at least one threonate and combinations of these.

[00027] Vitamin C is one of several antioxidants and maintains collagen, a protein necessary for the formation of skin, ligaments and bones. Vitamin C also enhances the immune systems that helps heal wounds and mend fractures. Vitamin C also aids in resisting some types of bacterial and viral infections, as well as also aiding in the absorption of iron.

[00028] If Vitamin E is used, the preferred dosage is from about 50mg to about 5000 mg. Vitamin E is an antioxidant that protects cell membranes and other fat-soluble parts of the body. Vitamin E also plays a role in the body's ability to process glucose. In the last ten years, studies have clarified the function of Vitamin E in the cells. In addition to its antioxidant functions, Vitamin E is now known to act through other mechanisms, including direct effects on inflammation, blood cell regulation, connective tissue growth, and genetic control of cell division, improve circulation, and allow the muscles to use oxygen. Vitamin E is found naturally in wheat germ oil, nuts and seeds, whole grains, egg yolks, and leafy green vegetables and certain vegetable oils. The names of all types of vitamin E begin with either d or dl, which refer to differences in chemical structure. The d form is natural and also known as RRR-alpha tocopherol and dl is a synthetic version, more correctly known as all-rac-alpha tocopherol. The natural form is more active and better absorbed by the body.

Vitamin E is traditionally measured in international units (IU). 100 IU of Vitamin E requires about 67 mg of the natural form, but closer to 100 mg of the synthetic form.

[00029] The food bar uses 67 mg for 100 IU of the preferable natural Vitamin E. The Vitamin E can be a tocopherol or tocopheryl followed by the name of what is attached to it, such as tocopheryl acetate. The most common forms of vitamin E are d-alpha tocopherol and d-alpha tocopheryl acetate or succinate and combinations or complexes thereof. The preferred Vitamin E is d-alpha tocopherol at 590 mg per dosage bar.

[00030] If Vitamin A is used, the preferred dosage is from about 250 mg to about 15,000 mg of Vitamin A. Vitamin A is fat-soluble vitamin. Retinol is one of the most active and usable forms of Vitamin A and is found in animal products, such as liver and eggs. Pro-vitamin A carotenoids are found in plant foods that contain darkly colored pigments that are converted to Vitamin A. Approximately 26% to 34% of Vitamin A consumed by men and women in the United States is provided by pro-vitamin A carotenoids. Beta-carotene is a pro-vitamin A carotenoid that is more efficiently converted to retinol than other carotenoids. The preferred Vitamin A is beta-carotene. The preferred dosage is 15,000 iu.

[00031] In a preferred embodiment, about 1000 mg to about 2000 mg by weight of 2-amino-2-deoxyglucose sulfate; 2-amino-2-deoxyglucose sulfate hydrochloride; n-acetyl 2-amino-2-deoxyglucose sulfate; or combinations thereof are used in the food bar. The most preferred dosage is from about 1200 mg to about 1500 mg.

[00032] The food bar can also include an amount of a binder, such as from about 1 mg to about 20 mg of a fat. The fat can be a saturated fat, a polysaturated fat, a monosaturated fat, a hydrogenated fat, a polyunsaturated fat, or an Omega 3 fatty acid. Saturated fats are solids at room temperature and turn to oil when heated. Most saturated fats are come from meat, poultry, and dairy products. Polyunsaturated fats originate from plant sources and are liquid at room temperature, such as vegetable oils from safflower, sunflower, sesame, cottonseed, corn oil and the like. Monounsaturated fats include olive oil, canola, and peanut oil and help decrease the

LDL levels of cholesterol. Hydrogenated fats begin as liquid fats but are solidified when hydrogen atoms are added. Most hydrogenated fats are partially hydrogenated vegetable oils. Monosaturated fats are the preferred fats to be used as a binder.

[00033] Omega 3 fatty acids also aid in the prevention or musculoskeletal disorders, lower cholesterol and triglyceride levels and reduce the risk of blood clot formation. Omega 3 fatty acids are essential fatty acids that our bodies cannot make by themselves and must be obtained from consumed food. Fish oils, derived from mackerel, lake trout, herring, sardines, albacore tuna and salmon, are also high in two kinds of Omega-3 fatty acids: eicosapentaenoic acid and docosahexaenoic acid.

[00034] Omega-3 fatty acids from plant sources include tofu and other forms of soybeans, canola, walnut and flaxseed. Their oils also contain alpha-linolenic acid, another form of omega-3 fatty acid. Omega 3 fatty acids used in the food bar can also be derived from pumpkin seeds, almonds, sesame seeds, walnuts, or combinations of these fatty acids.

[00035] From about 1000 mg to about 9000 mg of fiber can be used in the food bar. Fiber is the elongated, threadlike structures in fruits, vegetables, and grains that cannot be digested. Fiber has long been recognized as one of the best food ingredients for maintaining bowel regularity and preventing constipation.

[00036] The two types of fiber are water-soluble and insoluble. Water-soluble fiber dissolves in water and is found in oat bran, legumes, psyllium, nuts, beans, pectins, and various fruits and vegetables. Water-soluble fiber forms a bulky gel in the intestine that regulates the flow of waste materials through the digestive tract. Insoluble fiber cannot be dissolved in water, meaning that our bodies cannot digest it. Insoluble fiber includes the undissolvable parts of plant walls and is found in greatest amounts in cereals, brans, and vegetables. The primary function of insoluble fiber is to collect water that increases stool bulk in the large intestine. Soluble and insoluble fiber can be used alone or in combination.

[00037] The food bar in still another embodiment can include flavoring additives such as natural and artificial extracts, sweeteners, sugars, syrups and flavorings in portions from about 250 mg to about 5,000 mg.

[00038] The syrups used in the food bar can be selected for the following list: molasses, maple syrup, honey, corn syrup, high fructose corn syrup and inverted sugar. Molasses is a viscous liquid, containing sucrose, invert sugar, minerals and color, which is a by-product of sugar refining. Maple syrup is prepared from the sap of maple trees by boiling and evaporating to reduce the moisture content. Honey is a mixture of glucose and fructose that is collected from beehives. Corn syrup is glucose syrup that is made from the acid or enzyme hydrolysis of cornstarch. High fructose corn syrup results from enzyme hydrolysis of corn syrup to produce a product with 55-90% fructose. Invert sugar is formed from the partial or complete hydrolysis of sugar using heat, water and acid and/or invertase enzyme.

[00039] Artificial sweeteners can be used in the supplemental food bar. Examples of artificial sweeteners are aspartamane, sucralose and acesulfamine-K. Most artificial sweeteners are generally hundreds of times sweeter than sugar, and provide sweetening without calories. Aspartame is approximately two hundred times sweeter than sucrose. Acesulfame-K is two hundred times sweeter than sucrose and does not break down with heat, but requires the addition of some sucrose or other sweeteners to reduce its bitter, metallic flavor that may occur. Sucralose is produced by the selective chlorination of the sucrose molecule. Sucralose is six hundred times sweeter than sugar and is free of calories. Saccharine is produced artificially by the oxidation of a sulphamic derivative of toluene. Saccharine is one of the sweetest substances known with over two hundred times the sweetening power of sugar.

[00040] Examples of usable sugars include dextrose, maple sugar, cane sugar, beet sugar, a fructose, a sucrose, raw sugar, brown sugar, granulated sugar, glucose, maltose, lactose and combinations of these sugars. Granulated sugar can be extracted from both sugar cane and sugar beets.

[00041] Raw sugar is not fully refined and usually contains about 97% sucrose and 3% non-sugar compounds. Treating white sugar crystals with molasses syrup and blending the mix prepare brown sugar. Sucrose or table sugar is a disaccharide that is composed of one glucose molecule and one fructose molecule. Sucrose can be broken down into two monosaccharides, glucose and fructose. Glucose is a sweetener that is less sweet than sucrose. Fructose is sweeter than sucrose. Maltose is a disaccharide that is derived from the hydrolysis of starch by amylase. Maltose is produced during the malting of grains, especially barley. Lactose is a disaccharide that is present in milk.

[00042] Flavorings can be added to the food bar, such as a raspberry flavoring, chocolate flavoring, vanilla flavoring, strawberry flavoring, apple flavoring, citrus flavoring, kiwi flavoring, banana flavoring, coconut, caramel flavoring, grape flavoring, blueberry flavoring, peanut and nut butters, almond flavoring, tart cherry flavoring, coffee flavoring, cinnamon, ginger, nutmeg, clove, ginger, peach flavoring, pear flavoring, or other herbs, nuts and fruits.

[00043] The grain in the food bar can be a nutritional grain. Examples of usable grains are quinoa, millet, spelt, buckwheat, kamut, corn, rice, wheat, barley, oats, amaranth, wheat, bulgur, rye and combinations of these grains.

[00044] Other additives can be used in the food bar, such as from about 50 mg to about 800 mg of a naturally produced sulfur compound like s-adenosylmethionine. The body manufactures s-adenosylmethionine from methionine, an amino acid found in protein-rich foods, and adenosine triphosphate, an energy-producing compound found in all cells. The s-adenosylmethionine molecule or a methyl group attaches itself to tissues and organs in the body providing a critical link in methylation. Methylation is a chemical reaction that occurs billions of times a second throughout the body, thereby promoting cell growth.

[00045] The composition can include the sulfur compounds methyl sulfonyl methane (MSM) and s-adenosylmethionine, either individually or in combination

[00046] The food bar can include minerals, such as from about 1 mg to about 20 mg of selenium, boron, manganese, magnesium and combinations thereof.

[00047] In still another embodiment, the food bar can include between from about 1 mg to about 20 mg of a digestive enzyme. Preferred digestive enzymes are bromelain, pepsin, amylase, protease, lipase, cellulase, lactase, alpha-g, glucoamylase, invertase, malt diastase, pectinase, xylanase, bromelain, betain, and trypsin. These digestive enzymes can be in combinations or alone for aiding digestion.

[00048] Enzymes help break down food proteins, carbohydrates, and lipids. Mammals digest all their food extra-cellularly. Digestive enzymes are secreted from cells lining the inner surfaces of the exocrine glands. The enzymes hydrolyze the macromolecules in food into small, soluble molecules that can be absorbed into cells.

[00049] Additionally, calcium can be included in the food bar in portions from about 250 mg to about 1500 mg. Examples of calcium usable in the supplement are calcium carbonate, calcium citrate, calcium lactate, calcium gluconate and combinations thereof.

[00050] The food bar can also include from about 10 mg to about 500 mg of a bioflavonoid. Examples of bioflavonoid are quercetin, grape seed extract and combinations of these bioflavonoids.

[00051] In still another embodiment, the food bar can contain from about 250 to about 1000 mg chondroitin.

[00052] Another embodiment relates to a method for improving joint mobility in a subject in need by administering to a person the food bar as described once a day.

[00053] The food bar can be prepared by baking, cooking, cold processing, micro-waving, or extrusion (an extruded bar).

[00054] The food bar can also include flavorings of fruit juice, vegetable juice, blends of juice, juice and concentrates of juice.

[00055] The preferred composition of a 70-gram food bar is as follows:

Ingredient	**Wt/%**
Glucosamine	2.00
Methylsufonylmethane	0.70
Nutritional Grains	3.0
Digestive Enzymes	0.20
Spirulina	3.84
Whey protein concentrate	14.58
Fiber	5.0
90% high fructose corn syrup	10.13
Vitamin Complex	24.0
Partially hydrogenated soybean oil and Fatty Acids	0.34
Honey	4.97
Water	9.80
Flavor powder	4.89
Flavoring	0.69
Citric acid	2.21
Aspartame	0.44
Potassium sorbate	0.19

Sodium acid pyrophosphate	0.49
Sorbitol	3.68
Polydextrose	8.85

[00056] Preferably, the vitamin complex in the preferred composition is made of 250 mg of a Vitamin B complex (niacin, calcium pantothenate, pyridoxine hydrochloride (Vitamin-B6), riboflavin (Vitamin-B2), Thiamin Hydrochloride (Vitamin-B1), folic acid, biotin, Vitamin B12); 500 mg of a Vitamin C complex (calcium ascorbate and threonate); 590 mg of a Vitamin E complex (d-alpha tochopheryl or tocopherol); 61.5 mg of a minerals complex (selenium 50mg, boron 1.5, manganese 10 mg); 300 mg of a Bioflavonoid Complex (quercetin/100 mg and grapeseed extract 200 mg); 15,000 mg of Beta Carotene; and 500 mg of Calcium Lactate.

[00057] To manufacture the food bar, sorbitol and flavoring powders are sifted through a fine mesh screen separately. The flavoring is blended with about 12.5% of the oil until they are mixed thoroughly. The rest of the oil is then blended with the flavor mixture for about 1 minute. The whey protein concentrate and the polydextrose are then added to the oil mixture and blended for 1 minute. The honey and sorbitol are then blended into the oil mixture for about 1 minute. The flavoring, and the aspartame, are then added to the oil mixture and blended for about 1 minute. The spirulina is then added and blended for about 1 minute.

[00058] The manufacturing continues by pre-blending the corn syrup, honey and citric acid and adding the blend to the oil mixture. The sodium acid pyrophosphate is then added and the resultant mixture blended for 3 minutes. The potassium sorbate is dissolved in the water at 60°C along with the vitamin complex, glucosamine and methylsulfonylmethane and then the water is cooled and added to the mixture and blended for about 3 minutes. The digestive enzymes are added to the mixture and blended for 1 minute. The nutritional grains and fiber are added to the mixture and

blended for 3 minutes. The resultant mixture is then preferably extruded and cut into bars weighing approximately 70 grams.

[00059] While this supplement has been described with emphasis on the preferred embodiments, it should be understood that within the scope of the appended claims, the supplement might be practiced other than as specifically described herein.